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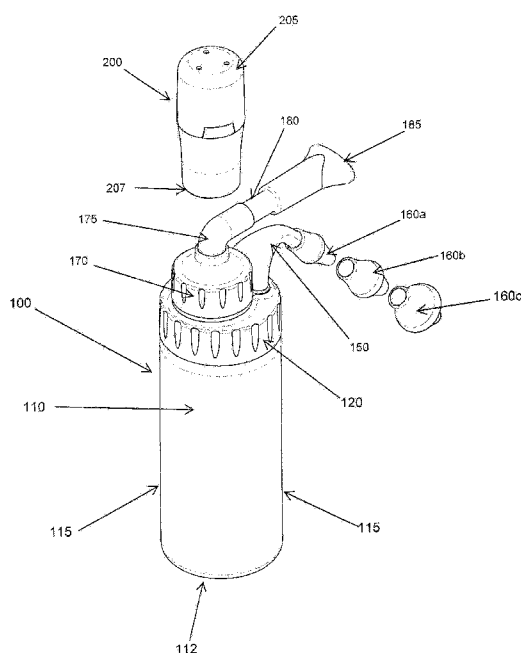
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 CATION MANAGEMENT SYSTEM

Fig. 1



(57) Abstract: A device, system and method are provided to accurately ap-
 ply a medically beneficial substance directly to a laterally or superiorly lo-
 cated paranasal sinus cavity. When the device is assembled with a solution
 in the reservoir, and inverted such that the reservoir is above the input appa-
 ratus and housing, the weight of the solution pushes down on a diaphragm
 creating a negative pressure on the diaphragm, which prevents air from enter-
 ing the reservoir and prevents liquid from flowing out of the reservoir.
 Applying a positive pressure to the bottom of the diaphragm causes the di-
 aphragm to open and allows air to flow into the reservoir. When a user cre-
 ates this positive pressure by exhaling air into the device it causes the user's
 choana to close. Thereby any solution introduced into the user's sino-nasal
 cavity will remain contained within a user's sino-nasal cavity increasing the
 effectiveness of the treatment and decreasing user discomfort including gag-
 ing, choking, and inner ear disturbance. When the positive pressure on the
 bottom of the diaphragm is removed, the flow of liquid from the reservoir
 container stops.

**SINO-NASAL RINSE DELIVERY DEVICE WITH AGITATION,
FLOW-CONTROL AND INTEGRATED MEDICATION
MANAGEMENT SYSTEM**

CROSS REFERENCE TO RELATED APPLICATION

[001] The present application claims the benefit of and priority to, under 35 U.S.C. §119(e), U.S. Provisional Application Ser. No. 62/691,010 filed on June 28, 2018 entitled “Sino-Nasal Rinse Delivery Device with Agitation, Flow-Control and Integrated Medication Management System”; U.S. Provisional Application Ser. No. 62/782,889 filed on December 20, 2018 entitled “Sino-Nasal Apparatus and Delivery Method Using Choanal Blockade and Electronic Agent Vaporization”; and, U.S. Provisional Application Ser. No. 62/782,898 filed on December 20, 2018 entitled “Eustachian Tube Dysfunction Treatment Method with Isolating, Incremental, Auto-Insufflation Pressure Generator”, which are hereby incorporated herein by reference in their entireties for all that they teach and for all purposes.

TECHNICAL FIELD

[002] Embodiments of the present disclosure relate to nasal and sinus devices. More specifically, embodiments of the disclosure relate to delivering an solution/substance to the nasal and sinus cavities.

BACKGROUND

[003] Paranasal sinuses are cavities formed within the bones of the face that are accessible via an individual's nasal cavity. The paranasal sinuses include the frontal sinuses, the sphenoid sinuses, the ethmoid sinuses, and the maxillary sinuses. Sino-nasal anatomy includes bilateral inferior, middle and supreme turbinate and the midline nasal septum. The paranasal sinuses and nose are lined with mucous-producing respiratory epithelial tissue.

[004] Normally, mucous produced by the linings of the sino-nasal sinuses slowly drains out of each sinus through an opening known as an ostium. Some conditions, however, can interfere with the drainage of the mucous. A healthy sino-nasal condition depends upon proper mucous drainage from the sinus cavities and the nose. When this natural process is disrupted by the effects of allergen, other bioactive particulate matter deposits or abnormal anatomic variations a condition of mucous stasis in the sinus cavities or the nose. As a consequence, nasal lining mucositis and/or sino-nasal disorders (*e.g.*, a sinus infection, sinus headache, epistaxis, nasal obstruction, rhinorrhea) can result. Some of the conventional systemic approaches to treating these disorders often result in cutaneous rash, diarrhea, bacterial resistance from antibiotic use, adrenal suppression, weight gain from steroid medications, hypertension, sleep disturbance from decongestant use, epistaxis, headache, vertigo and others.

[005] Surgery that is performed on the paranasal sinus cavities results in altered, modified or otherwise widened sinus drainage pathways compared to native outflow tracts.

[006] Direct application of a substance to a sinus through a nasal cavity may avoid some of the side-effects listed above that are inherent in a systemic approach to treating sinusitis, rhinitis and/or mucositis.

[007] However, due to the lateral or superior location of sinus outflow tracts the introduction of a substance via a trans-nasal route may result in a large majority of the substance bypassing the intended sinus cavity ostia.

[008] More specifically, the post-surgical maxillary sinus ostia is located on the lateral nasal wall approximately 3.0 to 4.0 centimeters from the apex of the external nasal vestibule and approximately at a 45 degree angle with respect to the floor of the nose. Thus, a substance delivered using a device introduced into the nose at approximately 45 degrees from the floor of the nose with an approximate length of 3 to 4 centimeters and with the capability of directing a substance at an 80 to 90 degree angle relative to the device itself would have the capability of directly delivering a substance to the maxillary sinus cavity when properly oriented.

[009] Additionally, the post-surgical frontal sinus outflow tract is located superiorly in the nasal cavity at approximately 5 to 6 centimeters from the apex of the external nasal vestibule at approximately 75° to 85° relative to the floor of the

nose. Thus, a substance delivered using a device introduced into the nose at approximately 45 degrees from the floor of the nose with an approximate length of 3 to 4 centimeters and with the capability of directing a substance at an 80 to 90 degree angle relative to the device itself would have the capability of directly delivering a substance to the frontal sinus cavity when properly oriented.

[0010] Accordingly, there is a need for a device, system, and method of treatment that has the capability to quickly and accurately apply a substance directly to a laterally or superiorly located paranasal sinus outflow tract. The present disclosure discusses a device that satisfies such needs, among the others delineated.

[0011] Direct application of a substance to an infected sinus through a nasal cavity will avoid some of the side-effects listed above that are inherent in a systemic approach. However, the introduction of a substance via a trans-nasal route may result in a large majority of the substance flowing down the individual's throat, resulting in possible aspiration, coughing and or choking; if the substance enters the oral cavity it also is distasteful, which further exacerbates the unpleasantness. Additionally, if a substance is forcibly introduced into a nasal cavity it is possible to overcome physiologic proximal Eustachian tube resistance resulting in the substance contaminating the middle-ear. The presence of a substance (other than physiologic body-temperature aeration) in the middle-ear may result in aural fullness, otitis effusion, otitis media, hearing loss (possibly

permanent), ossicular chain injury, damage to the middle-ear mucosal lining, dizziness/unsteadiness, nystagmus, nausea and others.

[0012] Accordingly, there is a need for a device and/or system that has the capability to quickly and accurately apply a substance to a paranasal sinus and/or sino-nasal cavity, prevent the substance applied to a paranasal sinus and/or sino-nasal cavity from flowing down a patient's throat and/or prevent the substance from contaminating the middle-ear cavity. The present disclosure discusses a device that satisfies such needs, among the others delineated.

[0013] Agents used in medicated sinus lavage are commonly supplied in capsule or other form; many individuals with dexterity problems are unable to manage the delivery of medication supplied in capsule or other form into sinus irrigation solution.

[0014] With respect to solubility of agents administered as a sinus lavage, there exist a category of agents that are immiscible in an aqueous or saline environment therefore presenting a challenge to delivery of a consistent agent concentration.

[0015] The use of saline or other sino-nasal irrigation solution delivered in a non-linear, turbulent, or pulsatile manner provides potentially additional cleansing properties over a solution delivered as a constant, uniform stream.

[0016] The effective use of gravity-assist sino-nasal lavage can be limited by an inability to control the flow of irrigation solution due to the siphon effect, *i.e.* a tube used to convey liquid upwards from a reservoir and then flows down to a lower level due to gravity, once the liquid has been forced into the tube and elevated, flow continues unaided and cannot easily be controlled or stopped.

[0017] The effective use of gravity-assist sino-nasal lavage can be further limited by an inability to extend the neck and look upwards, as is required in the application of conventional sino-nasal irrigation systems that rely on gravity to dispense the solution. This limitation is particularly acute for persons with neck extension limitations or persons who experience dizziness in this position, in particular elderly persons.

[0018] Sino-nasal rinsing can be limited by design features that are selective for specific anatomy, specifically that of adult versus children.

SUMMARY

[0019] Embodiments of the disclosure relate to delivering a pharmaceutically acceptable buffer preferably consisting of sterile saline solution or a solution with a therapeutically effective concentration of a pharmaceutical to nasal and sinus cavities. While multiple embodiments are disclosed, still other embodiments of the present disclosure will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative

embodiments of the disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

[0020] The sino-nasal irrigation device consists of a reservoir container; a housing with a grinding chamber and nose piece; and an input apparatus with a mouth piece. The reservoir container is intended for holding an solution. The housing has a grinding chamber for crushing capsules, pills, and the like, with an integrated filter separating the grinding chamber and the reservoir container that allows ground material of a predetermined size to pass through the filter and into the reservoir container. The housing also has a nose piece with a nasal tip and an optional nasal tip extension.

[0021] When the sino-nasal irrigation device is assembled with a solution in the reservoir container, and inverted such that the reservoir container is above the input apparatus and the housing, the weight of the solution in the reservoir container pushes down on the diaphragm creating a negative pressure on the diaphragm. The weight of the solution on the diaphragm prevents air from entering the reservoir container and thus prevents solution from the reservoir container from flowing out through the nose piece. Applying a positive pressure to the bottom of the diaphragm causes the diaphragm to open and allows air to flow into the reservoir container. The air flowing into the reservoir container causes turbulence in the solution held in the reservoir container resulting in the mixing of

the air and solution. The air flowing into the reservoir container also allows the solution in the reservoir container to flow out of the reservoir through the nose piece and into a user's nasal cavity. When the positive pressure on the bottom of the diaphragm is removed, the flow of liquid from the reservoir container stops.

DESCRIPTION OF THE DRAWINGS

[0022] The accompanying drawings are incorporated into and form a part of the specification to illustrate several examples of the present disclosure. These drawings, together with the description, explain the principles of the disclosure. The drawings simply illustrate preferred and alternative examples of how the disclosure may be made and used and are not to be construed as limiting the disclosure to only the illustrated and described examples. Further features and advantages will become apparent from the following, more detailed, description of the various aspects, embodiments, and configurations of the disclosure, as illustrated by the drawings referenced below.

[0023] FIG. 1 is a perspective view of an illustrative system for delivering an solution to the nasal cavity and or paranasal sinuses of a user, in accordance with the embodiments of the present disclosure.

[0024] Fig. 2 is an exploded perspective view of an illustrative system for delivering an solution to the nasal cavity or paranasal sinuses of a user, in accordance with the embodiments of the present disclosure.

[0025] Fig. 3a is a top view of the nasal tips 160a to accommodate the customary nasal opening sizes of children, 160b adults generally, and 160c for larger adults.

[0026] Fig 3b is a bottom view of the nasal tips 160a to accommodate the customary nasal opening sizes of children, 160b adults generally, and 160c for larger adults.

[0027] Fig. 3c is a sideview of the nasal tips 160a to accommodate the customary nasal opening sizes of children, 160b adults generally, and 160c for larger adults which are generally circular and thus the view from all sides is the same.

[0028] Fig. 4 is a bottom view of the input apparatus (170).

[0029] Fig. 5a is a top view of the housing (120).

[0030] Fig. 5b is a bottom view of the housing (120).

[0031] Fig. 6a is a view of the first distal end (205) of the mortar (200).

[0032] Fig. 6b is a view of the second distal end (207) of the mortar (200).

[0033] Fig. 7 is a cross-sectional view of a patient's head with an embodiment of the system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a nasal tip (160).

[0034] Fig. 8 is a cross-sectional view of a patient's head with an embodiment of the system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a nasal tip for directional flow (167) adapted to a user's nasal cavity by angling 80° to 90° degrees above the horizontal axis.

[0035] Fig. 9 is a cross-sectional view of a patient's head with an embodiment of the system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a nasal tip for directional flow (167) adapted to a user's nasal cavity by angling 80° to 90° degrees above the horizontal axis.

[0036] Fig. 10 is a flow chart detailing a preferred method of using the invention disclosed herein.

[0037] Fig. 11 is a perspective view of an alternative embodiment of illustrative system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a base for heating and mixing the solution, in accordance with the embodiments of the present disclosure.

[0038] Fig. 12 is a perspective view of an alternative embodiment of illustrative system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a base for heating and stirring the solution, in accordance with the embodiments of the present disclosure.

[0039] Fig. 13 is a partially exploded perspective view of an alternative embodiment of the illustrative system for delivering an solution to the nasal cavity and or paranasal sinuses of a user with a partial cross-section of the bottom.

[0040] Fig. 14 is a prospective view of the base (700).

DETAILED DESCRIPTION

[0041] Before any embodiments of the disclosure are explained in detail, it is to be understood that the disclosure is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the drawings. The disclosure is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting.

[0042] While the disclosed subject matter is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the disclosure to the particular embodiments described. To the contrary, the disclosure is intended to cover all modifications, equivalents, and alternatives falling within the scope of the disclosure as defined by the appended claims.

[0043] The term “solution” as used herein means a liquid; water; a pharmaceutically acceptable buffer solution, preferably consisting of a saline solution and more preferably still a sterile saline solution; and, a solution with a therapeutically effective concentration of a pharmaceutical. The pharmaceutical compound portion of the solution may be a salt, solid, liquid, or a gas (including a vapor). The pharmaceutical compound may be selected from any of the biopharmaceutical classes of the Biopharmaceutical Classification System (BCS) where Class 1 has high permeability and high solubility to Class 4 which has low permeability to low solubility. The solution containing a pharmaceutical compound may be an unsaturated solution, a saturated solution, a supersaturated solution, a mixture of two or more substances that are not chemically combined, a homogenous solution, a heterogeneous solution, a suspension, or an emulsion.

[0044] The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0045] As the terms are used herein with respect to ranges of measurements (such as those described above), “about” and “approximately” may be used interchangeably, to refer to a measurement that includes the stated measurement and that also includes any measurements that are reasonably close to the stated measurement, but that may differ by a reasonably small amount such as

will be understood, and readily ascertained, by individuals having ordinary skill in the relevant arts to be attributable to measurement error, differences in measurement and/or manufacturing equipment calibration, human error in reading and/or setting measurements, adjustments made to optimize performance and/or structural parameters in view of differences in measurements associated with other components, particular implementation scenarios, imprecise adjustment and/or manipulation of objects by a person or machine, and/or the like.

[0046] Although the term “block” may be used herein to connote different elements illustratively employed, the term should not be interpreted as implying any requirement of, or particular order among or between, various steps disclosed herein unless and except when explicitly referring to the order of individual steps. Additionally, a “set” or “group” of items (*e.g.* inputs, algorithms, data values, *etc.*) may include one or more items, and, similarly, a subset or subgroup of items may include one or more items.

[0047] The term “means” as used herein shall be given its broadest possible interpretation in accordance with 35 U.S.C. Section 112(f). Accordingly, a claim incorporating the term “means” shall cover all structures, materials, or acts set forth herein, and all of the equivalents thereof. Further, the structures, materials or acts and the equivalents thereof shall include all those described in the summary

of the invention, brief description of the drawings, detailed description, abstract, and claims themselves.

Sino-Nasal Irrigation Device

[0048] Referring to Figures. 1 to 8, the sino-nasal irrigation device (100) consists of a reservoir container (110), a housing (120) that is removably connected to the reservoir container (110) having a grinding chamber (125), a nose tube (150), and an input device (170) that is removably connected to the housing (120).

[0049] The reservoir container (110) in the preferred embodiment has a hollow interior cavity adapted to contain an solution and has a base (112). The reservoir container (110) has a curved sidewall (115) that extends substantially perpendicular to the base (112) to the open top (117) of the reservoir container (110) thereby defining the hollow interior cavity. The reservoir container (110) is adapted to removably engage the housing (120). In the preferred embodiment the reservoir container (110) has male threads (118) to threadingly mate with the housing (120). The reservoir container (110) may be of any shape or size including a round bulbous shape, a square or a rectangle.

[0050] The housing (120) is removable attachable to the reservoir container (110). In the preferred embodiment the housing (120) has female threads (124) to threadably mate with the reservoir container (110). The top of the housing

(122) has a grinding chamber (125) and a nose piece aperture (140). The grinding chamber (125) has a sidewall (128) that is preferably curved and extending substantially perpendicular to the top of the housing (122). The grinding chamber (125) has a filter (135) at the base that is integrated into the housing top (122) consisting of a plurality of holes (138) that will allow ground material of a defined size and water or a solution to pass through the filter (135). The plurality of holes (138) may be of uniform size or varying size. In the preferred embodiment the plurality of holes (138) are of varying size ranging from 1/8th of an inch in diameter to 3/16th of an inch in diameter.

[0051] In an alternative preferred embodiment other substances including powders, liquids, gaseous and vapors may be introduced into the reservoir container (110) through the filter integrated into the grinding chamber (135) or by bypassing the grinding chamber (125) and introduced directly into the solution in the reservoir container (110). In an alternative preferred embodiment a vapor pod (not shown) may be removably attached to the air tube (180) so that when a user exhales into the mouth piece (185) on the input apparatus (170) air and vapor from the vapor pod creates a positive pressure in the air tube (180) and air and vapor passes through the diaphragm (190) and into the reservoir container (110) where the vapor mixes with and dissolves into the solution. The introduction of air and vapor into the reservoir container (110) displacing the

solution held in the reservoir container (110) out the nose tube (150) through the nasal tip (160).

[0052] The grinding chamber (125) also has a plurality of grinding teeth (130) that extend substantially perpendicular to the filter (135). The plurality of grinding teeth (130) may be of either uniform size and shape or varied size and shape. In the preferred embodiment the plurality of grinding teeth (130) consist of a plurality of cured grinding teeth (131) spaced equal distantly in a circular pattern in the grinding chamber (125) and a plurality of wedge shaped grinding teeth (132) located within the circular pattern formed by the curved grinding teeth (131).

[0053] The nose tube (150) is attached to the nose piece aperture (140) in the housing top (122). In the preferred embodiment the nose piece aperture (140) is a curve-linear oval shape. The nose tube (150) is preferably substantially rigid and curved such that when the sino-nasal device (100) is inverted the mouth piece (185) is proximate a user's mouth then the distal end of the nose tube (150) is proximate a user's nose bench. The nose tube (150) has a removable nasal tip (160) at the distal end of the nose tube (150). The nasal tip (160) frictionally engages the nose tube (150) and thus is adjustable and may be positioned in a preferable location for each user. The nasal tip (160) may be removed from the nose tube (150) for cleaning or replacement. The nasal tip (160) has various sizes

and shapes (160a – 160c) to accommodate the customary nasal opening sizes of children (160a), adults (160b), and larger adults (160c).

[0054] An alternative preferred embodiment may include a nasal tip for directional flow (167) that frictionally engage the nose tube (150) or the nasal tip aperture opening (165) to provide for a more controlled and direction application of medicine and/or solution to a surgical site, wound, or by user preference. The nasal tip for directional flow (167) is preferably flexible with a blunt terminal end (168) with a plurality of aperture openings (169) proximate to the terminal end that are preferably 2 to 4 mm in length and more preferably 1 to 2 mm in length. The plurality of aperture openings (169) are preferably oval, but may also be substantially circular or substantially square in order to provide a desired flow rate of solution in a preferred direction. The nasal tip for directional flow (167) are preferably 1 to 4 cm length, and more preferably 1 to 2 cm length. The exposed length of nasal tip for directional flow (167) may also be controlled by how far the nasal tip for directional flow (167) is inserted on the nose tube (150), or alternatively, into the tip aperture opening (165) in order to maximize the delivery of medicine and/or solution to a surgical site, wound, or by preference of a user.

[0055] The input apparatus (170) is removably attached to the grinding chamber (125) on the housing (120). In the preferred embodiment the input apparatus (170) has a hollow interior cavity (177) that is threaded to connect to the

exterior of the grinding chamber sidewall (128). When the input apparatus (170) is attached to the grinding chamber (125) the mouth piece (185) of the input device (170) should align with the nasal tip (160) of the housing (120) when assembled and closed. The input apparatus (170) is comprised of a mouth piece (185) that is frictionally attached to an air tube (180) so that the location of the mouth piece (185) may be configured in a preferred way for each user. The air tube (180) is also connected to the L-connector (175) of the input apparatus (170). In the preferred embodiment the air tube (180) connects in the center of the top of the L-connector (175) which is attached to the input apparatus (170). A diaphragm (190) is interposed at the terminal end of the air tube (180) where the air tube (180) connects to the input apparatus (170).

[0056] When the sino-nasal irrigation device is assembled with a solution in the reservoir container, the diaphragm (190) permits air into the reservoir container (110) when a positive pressure exists in the air tube (180) by allowing air to pass through the diaphragm (190). When a positive pressure does not exist in the air tube (180), then the diaphragm (190) prevents the flow of an solution in the reservoir container (110) from flowing pass the diaphragm (190) and out the input apparatus (170).

[0057] The mortar (200) has a first distal end (205) with a recess (210) containing a plurality of grinding teeth (205) and a second distal end (207) with a

plurality of tines (prongs) (225) that are covered by a frictionally engaged cap (220). In the preferred embodiment the plurality of grinding teeth (215) in the recess (210) in the first distal end (205) consist of a plurality of curved grinding teeth (215) spaced equal distantly in a circular pattern in the recess (210) and a square pike grinding tooth (210) in the center of the recess (210). The second distal end (207) has a plurality of tines (225) that may be sized or of variable sizes. In the preferred embodiment, the size and placement of the tines (225) matches the aperture size and pattern of the plurality of holes (138) in the filter integrated into the bottom of the grinding chamber (135) to facility the cleaning of the grinding chamber (135) by dislodging any material caught in the integrated filter (135) by pushing the tines (225) into underside of the integrated filter (135) in the housing top (122).

[0058] Referring to Figs 10 to 14, in an alternative preferred embodiment the reservoir container (610) has a hollow interior cavity adapted to contain an solution and has a threaded base cap (615) to be removably connected to the reservoir container (610). The threaded base cap (615) can withstand direct radiant heating in the range of 75°F to 150°F and more preferably 80°F to 110°F without any chemical breakdown or leaching of the chemicals used to make the reservoir container (610) or threaded base cap (615). The threaded base cap (615) has a flexible barrier layer (630) that permits a temperature probe (730) from the

base station (700) to extend into the reservoir container (610) without coming in direct contact with the solution in the reservoir container (610). The reservoir container (110) has a curved sidewall (115) that extends substantially perpendicular to the base (112) to the open top (117) of the reservoir container (110) thereby defining the hollow interior cavity.

[0059] The base station (700) contains a logic engine that permits a user to input the desired temperature a user wants the solution in the reservoir container (610) warmed to. The temperature probe (730) takes a temperature reading, and then compares that temperature reading to the input temperature. If the temperature reading is below the input temperature, then the logic engine provides power to the base station heating sources (720) in order to raise the temperature of the solution to the input temperature. Once the solution reaches the input temperature, the logic engine may reduce power to the base station heating source (720) or turn the base station heating source off. The logic engine will continue to measure the temperature of the solution through the temperature probe (730) and apply heat as needed to maintain temperature. The temperature probe (730) is preferably a thermistor, thermocouple or similar temperature measuring probe. The base station heating source (720) is preferably resistive heating coils but may be any known heating source known to one of ordinary skill in the art.

[0060] The alternative preferred embodiment may also have indirect stirring means such as a magnetic stirrer consisting of one or more magnets in the base station and at least one magnet in the reservoir container that may be used to stir the solution to aid the dissolution of difficult to dissolve chemical compounds into solution.

[0061] The alternative preferred embodiment may also include an ultra-violet (UV) light source proximately located adjacent to the reservoir container (610) that will sterilize the water in the reservoir container (610).

Method of Using The Sino-Nasal Irrigation Device

[0062] The sino-nasal irrigation device (100) may be used by filling the reservoir container (110) with the desired amount of water. Preferably, and recommended, sterile water is used. Alternatively, denatured water may be used. The housing (120) is then removably engaged on the reservoir container (110).

[0063] Optionally, if a user wants to use an aqueous saline solution, then the user may place capsule(s) containing the equivalent of 2.4 grams of sodium chloride (NaCl) per 10 ounces of water into the grinding chamber (125) on the housing (120). Then, while firmly holding the reservoir container (110), the user engages the first distal end (205) of the mortar (200) with the grinding chamber (125) containing the capsule to grind the capsule and its contents to sufficiently fine size to pass through the filter integrated into the bottom of the

grinding chamber (135). Preferably, grinding of a capsule is achieved by twisting the mortar (200) in the grinding chamber (125) while applying downward pressure. Thereby allowing the ground capsule to form an solution in reservoir container (110). If the plurality of holes (138) in the filter (135) have become occluded with remnants of the capsule, then the plurality of holes (138) should be cleared by removing the housing (120) from the reservoir container (110) and pushing the tines (225) on the second distal end of the mortar (207) through plurality of holes from the underside of the integrated filter (135) in the housing top (122) to dislodge any material occluding the filter holes (135). The housing (120) is then removably engaged on the reservoir container (110). In an alternative preferred embodiment other substances including powders, liquids, gaseous and vapors may be introduced into the reservoir container (110) through the filter integrated into the grinding chamber (135) or by bypassing the grinding chamber (125) and directly into the substance into the reservoir container (110), thereby creating an solution.

[0064] The input apparatus (170) may then be removably engaged on the housing (120). The mouth piece (185) of the input apparatus (170) is aligned with the nasal tip (160) on the housing (120). The sino-nasal irrigation device (100) is then ready for treatment application.

[0065] The sino-nasal irrigation device (100) is then inverted such that the reservoir container (110) is above the input apparatus (170) and the housing

(120), the weight of the solution in the reservoir container (110) pushes down on the diaphragm (190) creating a negative pressure on the diaphragm (190). The weight of the solution on the diaphragm (190) prevents air from entering the reservoir container (110) and thus prevents liquid from the reservoir container (110) from flowing out through the nose tube (150). Applying a positive pressure to the bottom of the diaphragm (190) causes the diaphragm to open and allows air to flow into the reservoir container (110). The air flowing into the reservoir container (110) causes turbulence in the solution held in the reservoir container resulting in the mixing of the air and solution. The air flowing into the reservoir container also allows the liquid in the reservoir container (110) to flow out of the reservoir (110) through the nose tube (150) and into a user's nasal cavity. When the positive pressure on the bottom of the diaphragm (190) is removed, the flow of liquid from the reservoir container (110) stops.

[0066] When a user, blows or exhales against resistance, the user's soft palate/uvula elevates and contacts the posterior wall of the oro/nasopharynx, thereby closing the choana. This normal physiologic process effectively creates temporary anatomic isolation of the nasal cavity from the oral cavity, distal airway and glottis/proximal trachea. As such, any fluid that is introduced into the user's sino-nasal cavity, as described herein, will remain contained within a user's sino-

nasal cavity, being directed out the contralateral sino-nasal cavity, and not travel into the user's distal airway, glottis/superior trachea.

[0067] In an alternative preferred embodiment, a user blows or exhales against resistance to close the choana by blowing into the mouth piece (185) on the input apparatus (170), but the tube (180) is partially constrained allowing only a fraction of the air exhaled by the user to reach the reservoir container (110), or is fully constrained such that none of the air exhaled by the user reaches the reservoir container (110). When a positive pressure is detected in the tube (180) due to a user exhaling then a small pump (not shown) is activated to pump solution from the reservoir container (110) out the nose tube (150). When the positive pressure is removed, the pump is deactivated and the flow ceases. This alternative preferred embodiment may be used by those with compromised respiratory systems due to illness or other infirmity.

[0068] Referring to Figure 9, a method for using the preferred embodiment is provided for treating a patient (700). Block 710 provides for adding a prescribed amount of sterile, or purified, water to the reservoir container (110). Block 720 provides for the partial assembly of the sino-nasal irrigation device by removably connecting the housing (120) to the reservoir container (110). Block 730 grinding of a capsule, tablet, or the like in the grinding chamber (125) to form a powder fine enough to pass through the filter (135). Block 740 provides for

the forming of a solution by allowing the ground powder from the capsule, tablet, or the like to pass through the filter (135) and into the reservoir container (110) where the powder will be dissolved into the liquid to form a solution. Block 750 provides for the further assembly of the sino-nasal irrigation device by removably connecting the input apparatus (170) to the previously assembled reservoir container (110) and housing (120). Block 760 provides for the administration of the solution to a user by inverting the assembled sino-nasal irrigation device (100) so that the reservoir container (110) is above the housing (120) and input apparatus (170) such that any air remaining in the reservoir container (110) is proximate the base of the reservoir container (112), inserting the nasal tip (160) into a nostril of the user, and keeping the nasal tip inserted into a nostril of the user, blowing into the mouth piece (185) to provide a positive pressure in the air tube (180). The positive pressure in the air tube (180) causes air to pass through the diaphragm (190) and into the reservoir container (110) thereby displacing the solution held in the reservoir container (110) out the nose tube (150) through the nasal tip (160).

[0069] The foregoing discussion has been presented for purposes of illustration and description. The foregoing is not intended to limit the disclosure to the form or forms disclosed herein. In the foregoing Summary for example, various features of the disclosure are grouped together in one or more aspects, embodiments, and/or configurations for the purpose of streamlining the disclosure.

The features of the aspects, embodiments, and/or configurations of the disclosure may be combined in alternate aspects, embodiments, and/or configurations other than those discussed above. For example, the device(s) described in the present disclosure may be used in conjunction with other medical devices. This method of disclosure is not to be interpreted as reflecting an intention that the claims require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed aspect, embodiment, and/or configuration. Thus, the following claims are hereby incorporated into this Detailed Description, which each claim standing on its own as a separate preferred embodiment of the disclosure.

[0070] Moreover, though the general description of the invention has included detailed description of one or more aspects, embodiments, and/or configurations and certain variations and modifications, other variations, combinations, and modifications are within the scope of this disclosure, *e.g.*, as may be within the skill and knowledge of those in the art, after understanding the present disclosure. The intent is to obtain rights which include alternative aspects, embodiments, and/or configurations to the extent permitted, including alternate, inter-changeable and/or equivalent structures, functions, ranges or steps are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

CLAIMS

What is claimed is:

1. A device for delivering a solution to a sino-nasal cavity of a user, the device comprising:

5 a reservoir container;

a housing adapted to connect to the reservoir container wherein the housing has a nose tube and grinding means; and

an input apparatus adapted to connect to the housing wherein the input apparatus has a mouth piece connected to a tube and the tube is connected to the
10 input apparatus.

2. The device for delivering a solution to a sino-nasal cavity of a user of Claim 1 wherein the means for grinding a capsule is a grinding chamber with a filter in the housing and a plurality of grinding teeth extending substantially
15 perpendicular to the filter; and,

a mortar with a first distal end and a second distal end.

3. The device for delivering a solution to a sino-nasal cavity of a user of Claim 1 wherein the mouth piece is removably attached to a first terminal end of the tube and a diaphragm is interposed at a second terminal end of the tube that
5 connects to the input apparatus.

4. The device for delivering a solution to a sino-nasal cavity of a user of Claim 1 further comprising a mortar having a first distal end with a recess containing a plurality of grinding teeth and a second distal end with a plurality of
10 tines configured to align with the plurality of holes in the filter.

5. The device for delivering a solution to a sino-nasal cavity of a user of Claim 4 wherein the mortar further comprises a removable cap that frictionally engages the mortar and covers the tines on the second distal end of the mortar.

15

6. The device for delivering a solution to a sino-nasal cavity of a user of Claim 1 further comprising a tip with directional flow that is removably attached to the distal end of the nose tube.

7. A device for delivering a solution to a sino-nasal cavity of a user, the device comprising:

a reservoir container adapted to removably engage a housing wherein the housing has a nose piece with a nasal tip adapted to removably attach to a terminal end of the nose piece;

an input apparatus with a tube that connects a mouth piece to the input apparatus wherein the mouth piece is adapted to removably connect to the housing.

8. The device for delivering a solution to a sino-nasal cavity of a user of Claim 7 wherein the tube has a first terminal end with the mouth piece removably attached and a second terminal end that connects to the input apparatus with a diaphragm.

9. The device for delivering a solution to a sino-nasal cavity of a user of Claim 8 wherein the diaphragm permits air flow into the reservoir container when a positive pressure exists in the tube.

10. The device for delivering a solution to a sino-nasal cavity of a user of Claim 8 wherein the diaphragm prevents gravity flow of a solution from the reservoir container when a positive pressure does not exists in the air tube.

5

11. The device for delivering a solution to a sino-nasal cavity of a user of Claim 7 further comprising a nasal tip with directional flow adapted to removably engage the terminal end of the nose piece or the nasal tip.

10 12. The device for delivering a solution to a sino-nasal cavity of a user of Claim 7 wherein the housing has a grinding chamber with a filter comprising a plurality of holes in the housing.

15 13. The device for delivering a solution to a sino-nasal cavity of a user of Claim 7 further comprising a mortar with a first terminal end with a plurality of grinding teeth and a second terminal end with a plurality of tines.

14. The device for delivering a solution to a sino-nasal cavity of a user of Claim 13 wherein the plurality of tines on the second terminal end of the mortar
5 are configured to match the plurality of holes in the top of the housing comprising the filter.

15. The device for delivering a solution to a sino-nasal cavity of a user of Claim 7 wherein the nasal tip is selected from the group consisting of: a nasal tip
10 to accommodate the nasal opening sizes of children; a nasal tip to accommodate the nasal opening sizes of adults; and, a nasal tip to accommodate the nasal opening sizes of larger adults.

16. A device for delivering a solution to a sino-nasal cavity of a user, the
15 device comprising:

a reservoir container adapted to removably engage a housing wherein the housing has a nose piece with a nasal tip adapted to removably attach to a terminal end of the nose piece;

the housing further comprising a grinding chamber with a filter in the housing consisting of a plurality of holes in the housing and a plurality of grinding teeth extending substantially perpendicular to the a filter; and,

an input apparatus with a tube with a mouth piece at a first terminal end of the tube and a diaphragm at a second terminal end of the tube that connects to the input apparatus.

17. The device for delivering a solution to a sino-nasal cavity of a user of Claim 16 wherein the diaphragm has a first closed position that prevents gravity flow of a solution in the reservoir container when a positive pressure does not exists in the tube and a second open position that permits air flow into the reservoir container when a positive pressure exists in the tube.

18. The device for delivering a solution to a sino-nasal cavity of a user of Claim 16 further comprising a nasal tip with directional flow adapted to removably engage the terminal end of the nose tube or the nasal tip.

19. The device for delivering a solution to a sino-nasal cavity of a user of Claim 16 further comprising a mortar with a first terminal end with a plurality of grinding teeth and a second terminal end with a plurality of tines.

5 20. The device for delivering a solution to a sino-nasal cavity of a user of Claim 19 wherein the plurality of tines on the second terminal end of the mortar are configured to match the plurality of holes in the top of the housing comprising the filter.

10 21. An input device for use with a sino-nasal treatment device comprising:
an input apparatus with a tube having a first terminal end and a second terminal end that is connected to the input apparatus wherein a diaphragm is interposed at the second terminal end of the tube;

the diaphragm has a top side proximate the input apparatus and a bottom
15 side proximate the tube;

wherein the diaphragm has a first closed position that prevents flow through the tube when pressure is asserted on the top side of the diaphragm and a second open position that permits flow through the tube when pressure is asserted on the bottom side of the diaphragm.

Fig. 1

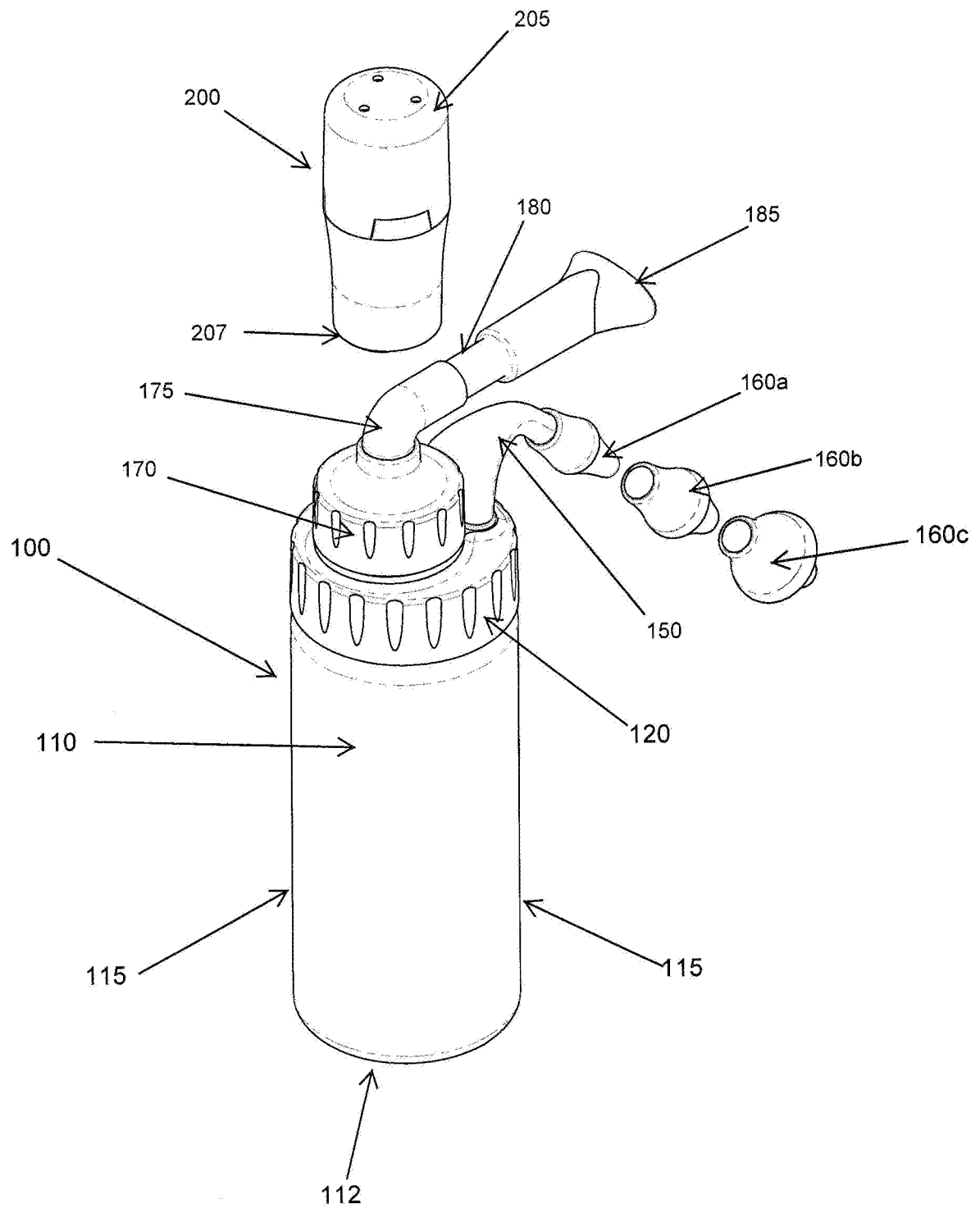


Fig. 2

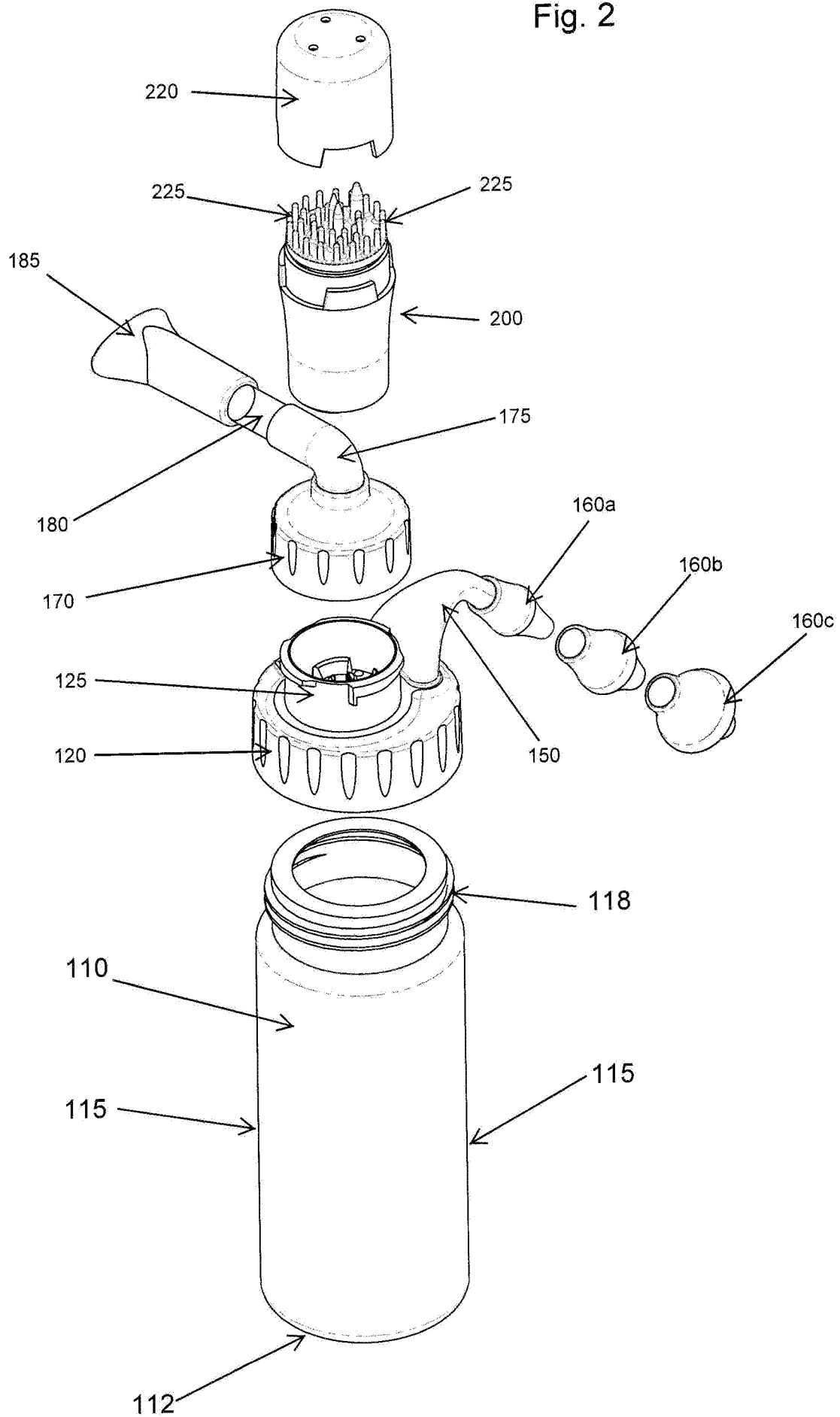


Fig. 3a

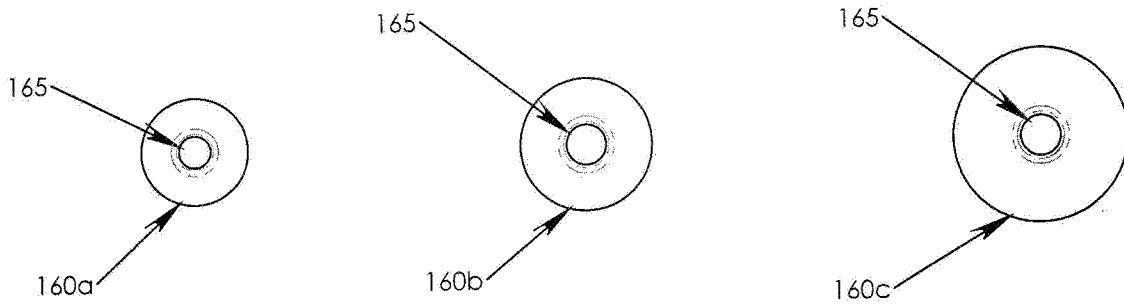


Fig. 3b

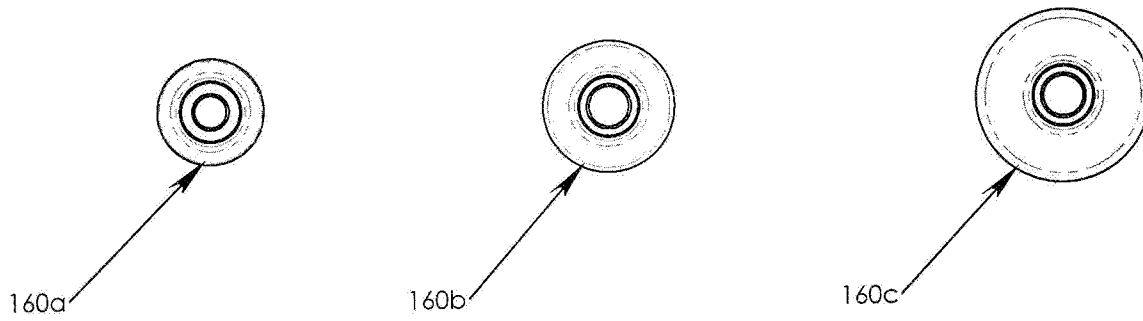


Fig. 3c

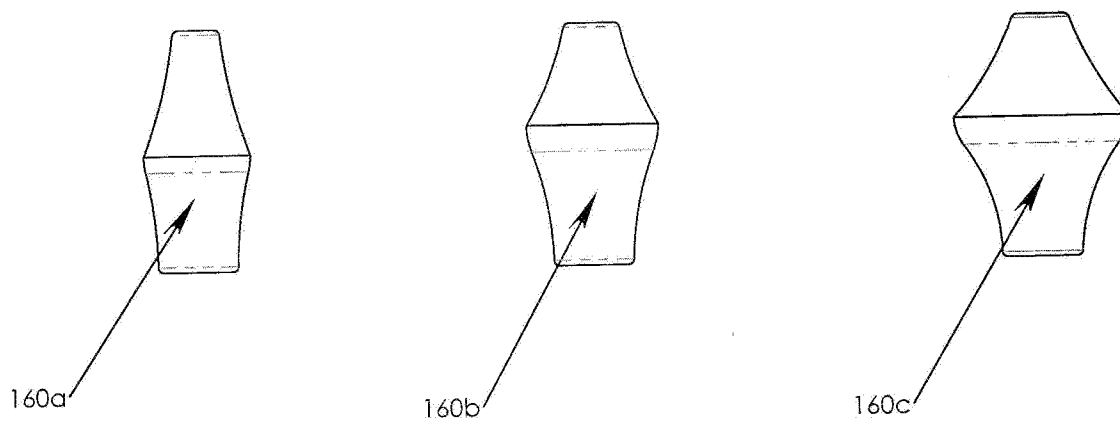


Fig. 4

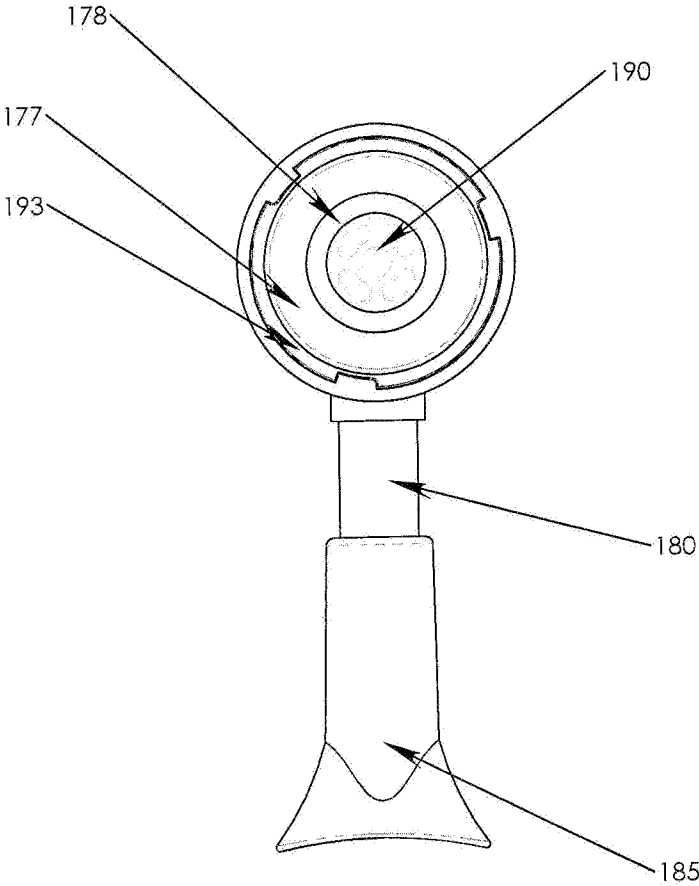


Fig. 5a

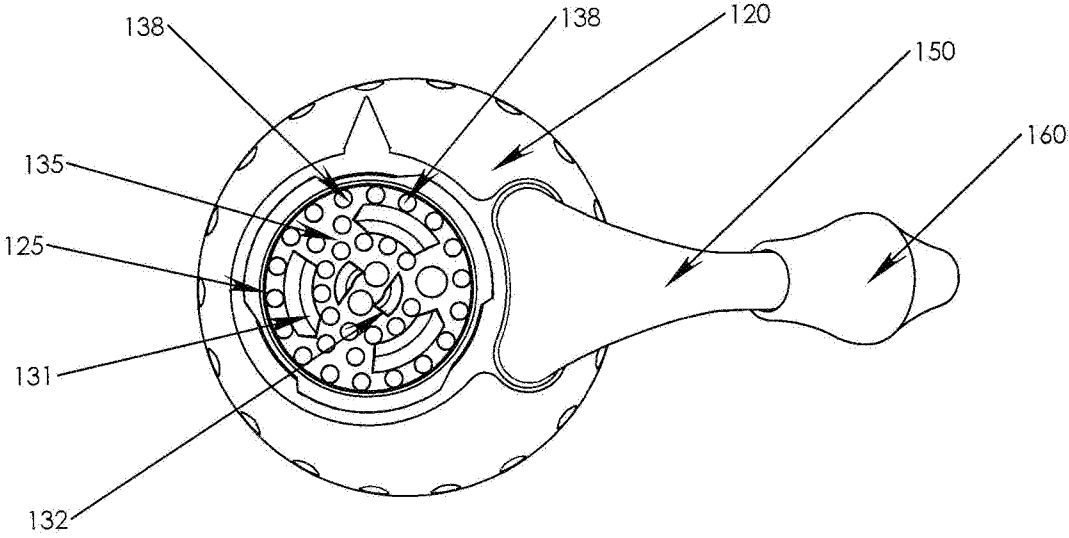


Fig. 5b

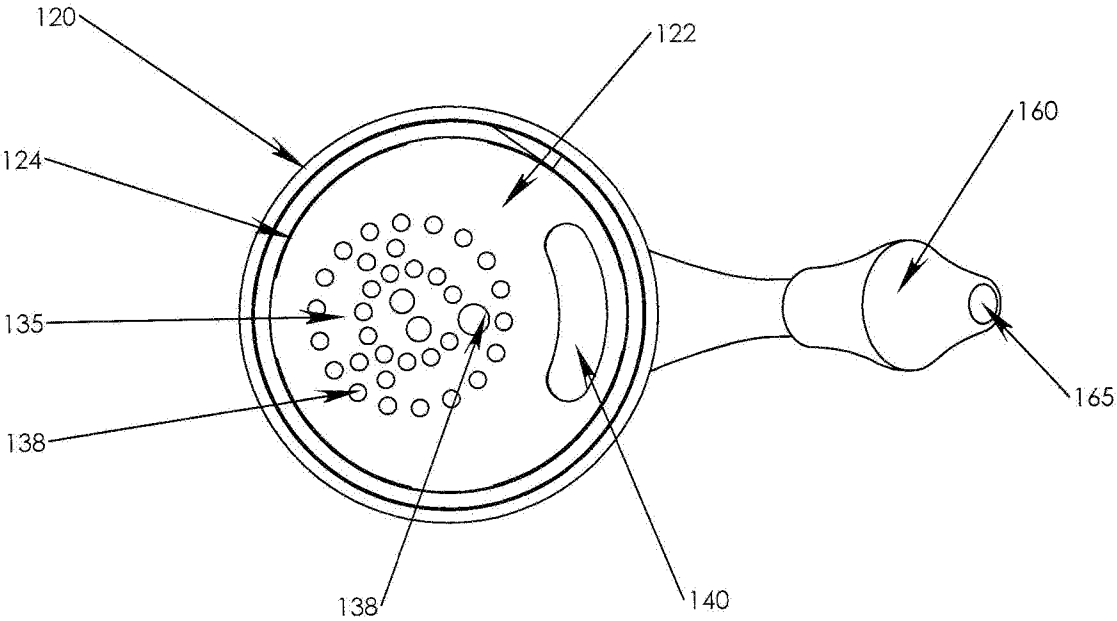


Fig. 6a

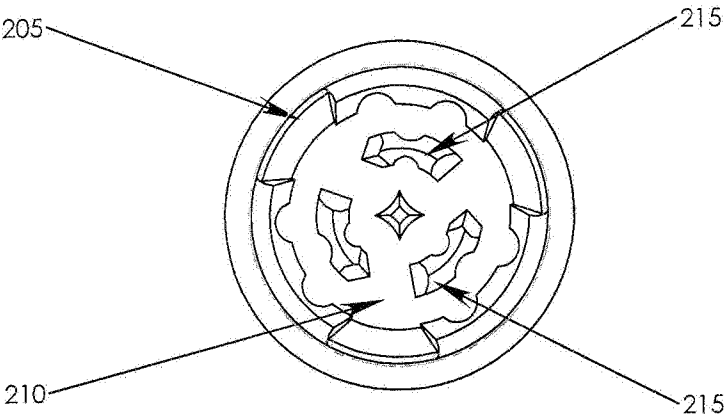


Fig. 6b

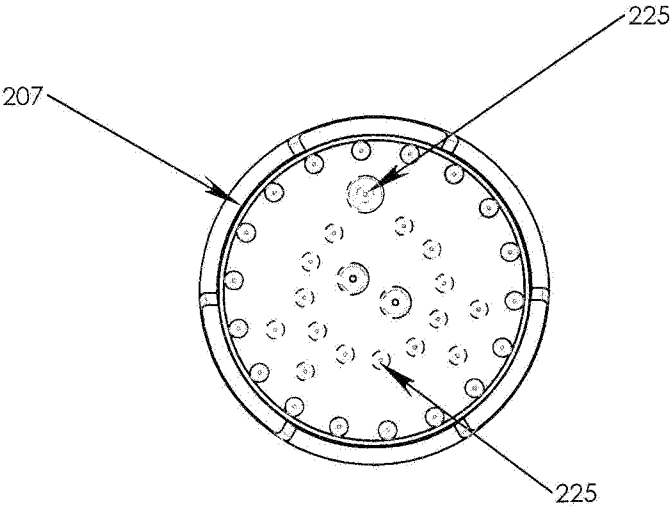


Fig. 7

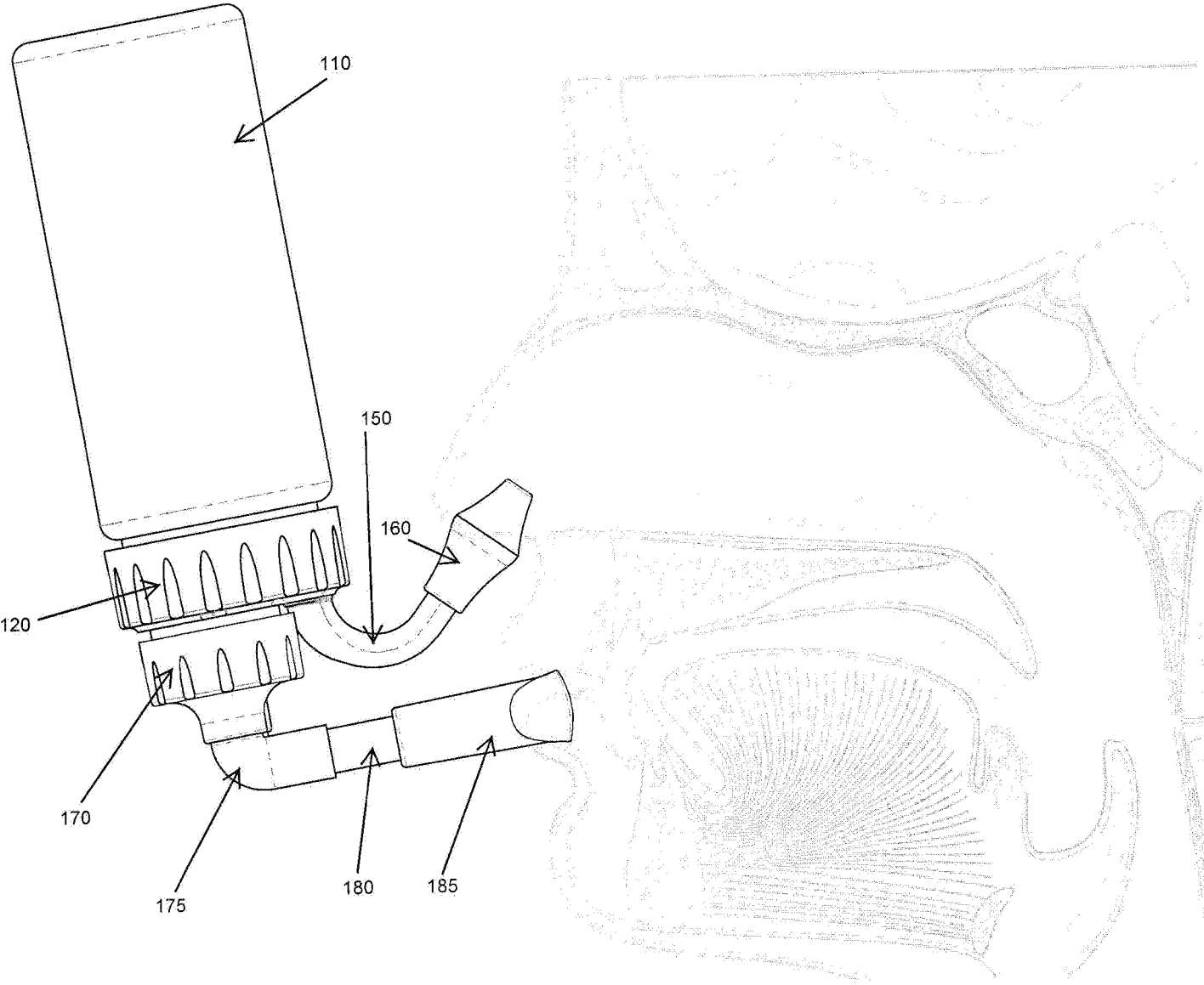


Fig. 8

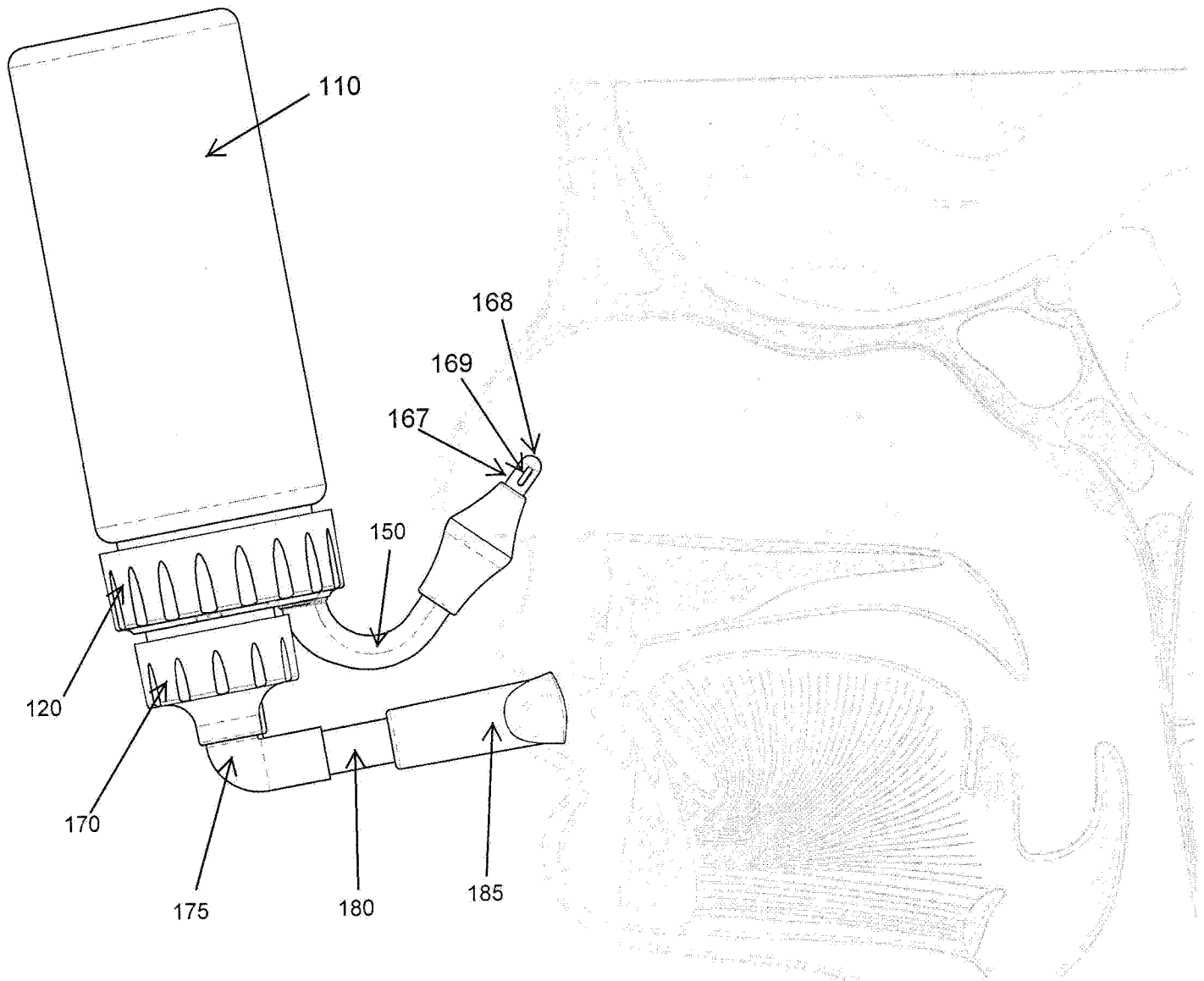


Fig. 9

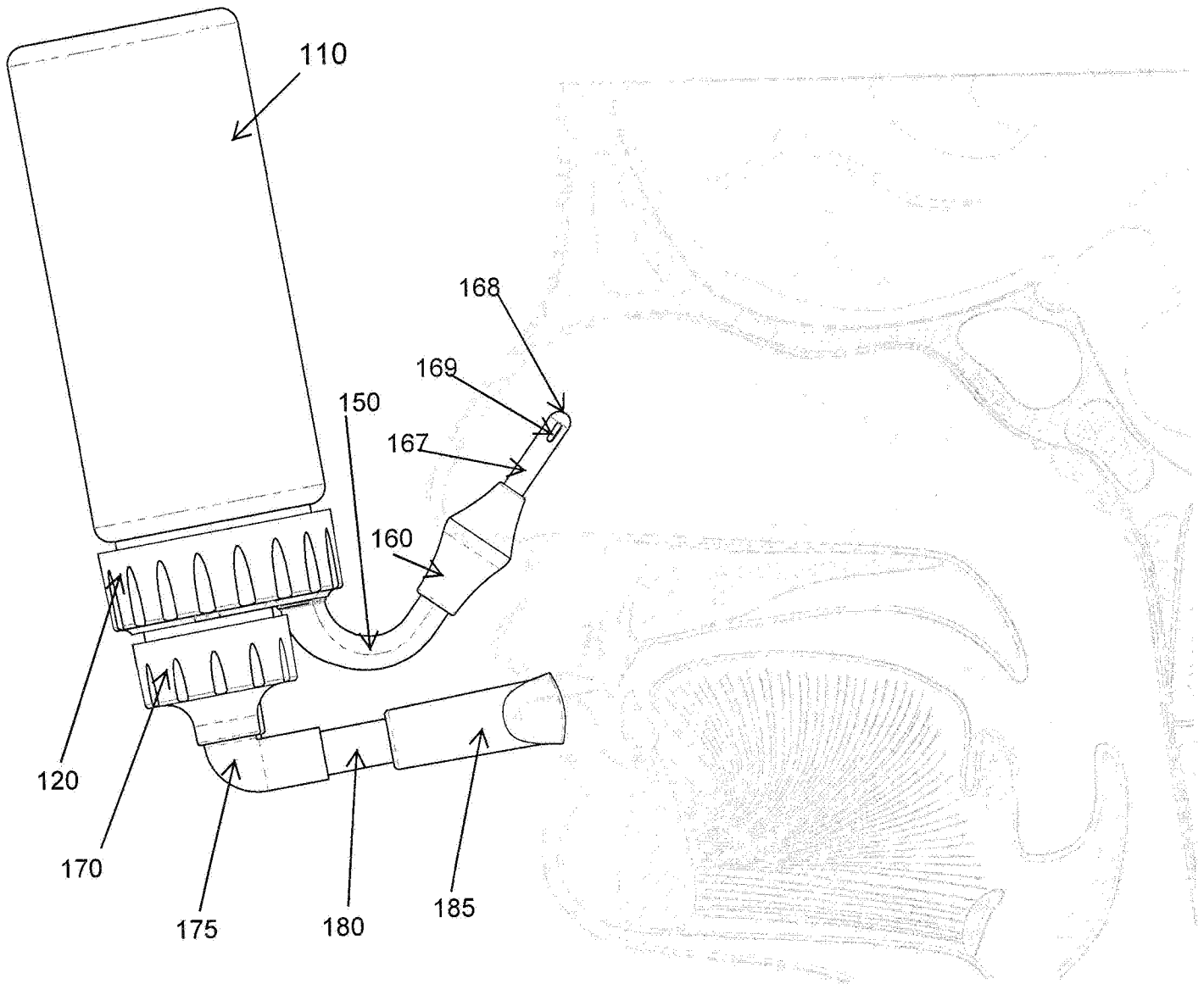


Fig. 10

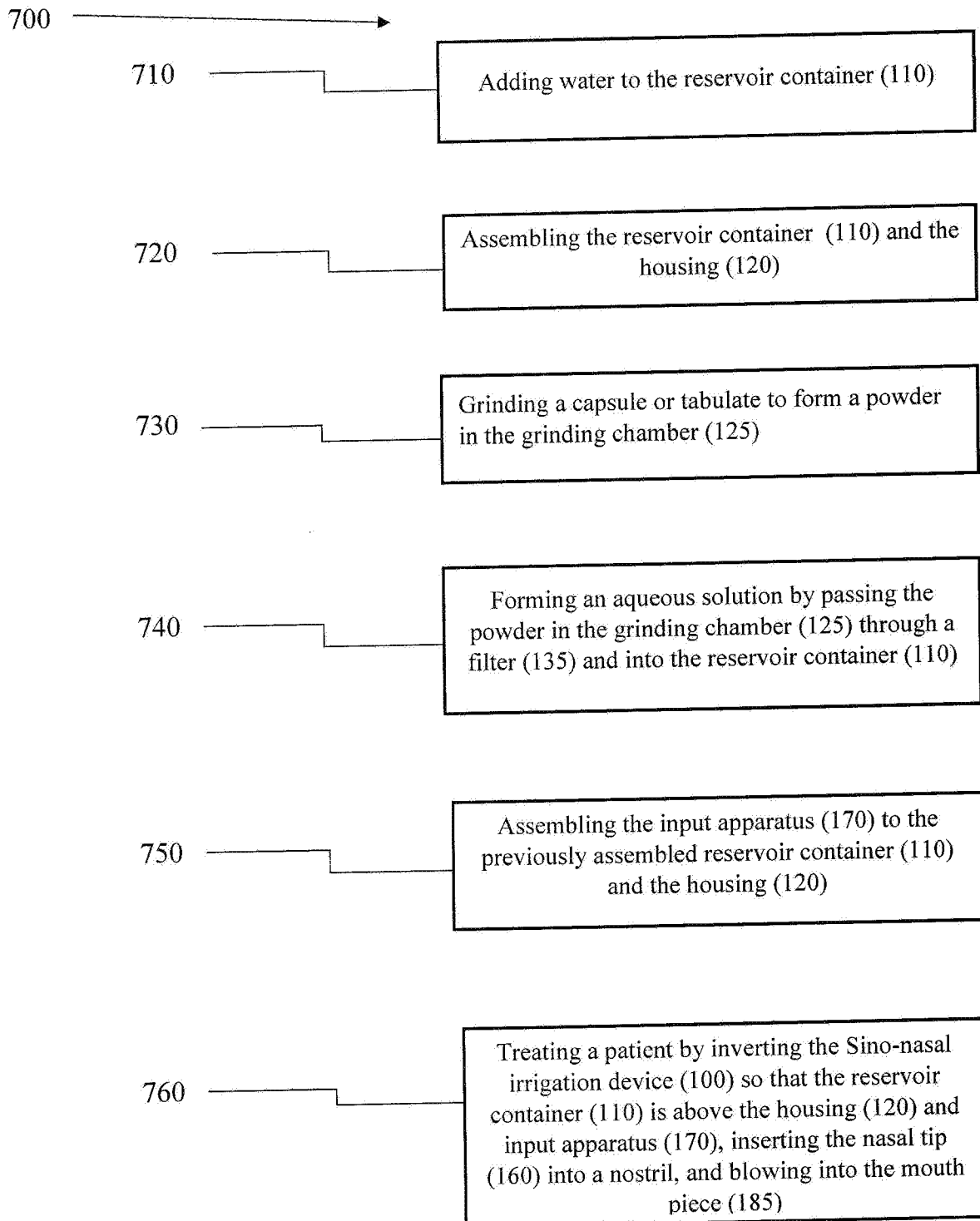


Fig. 11

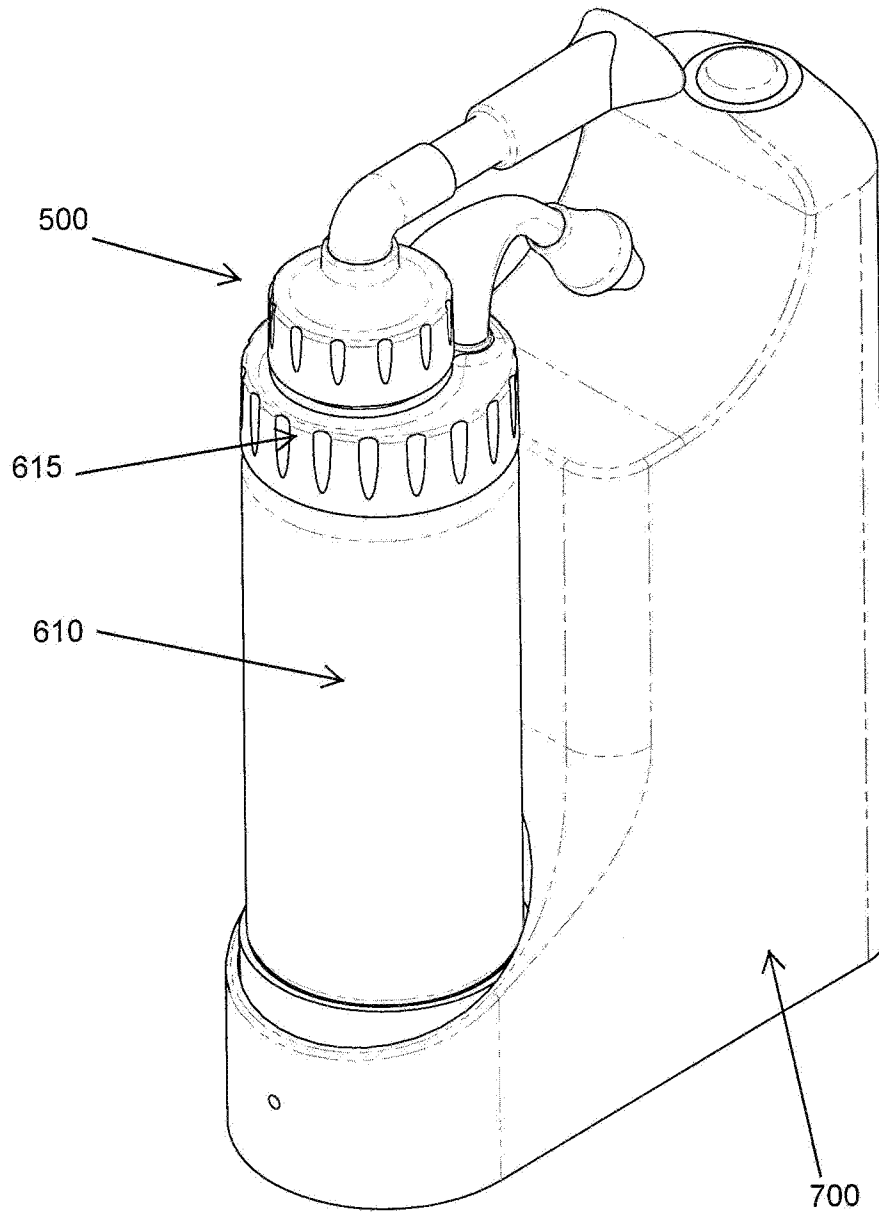


Fig. 12

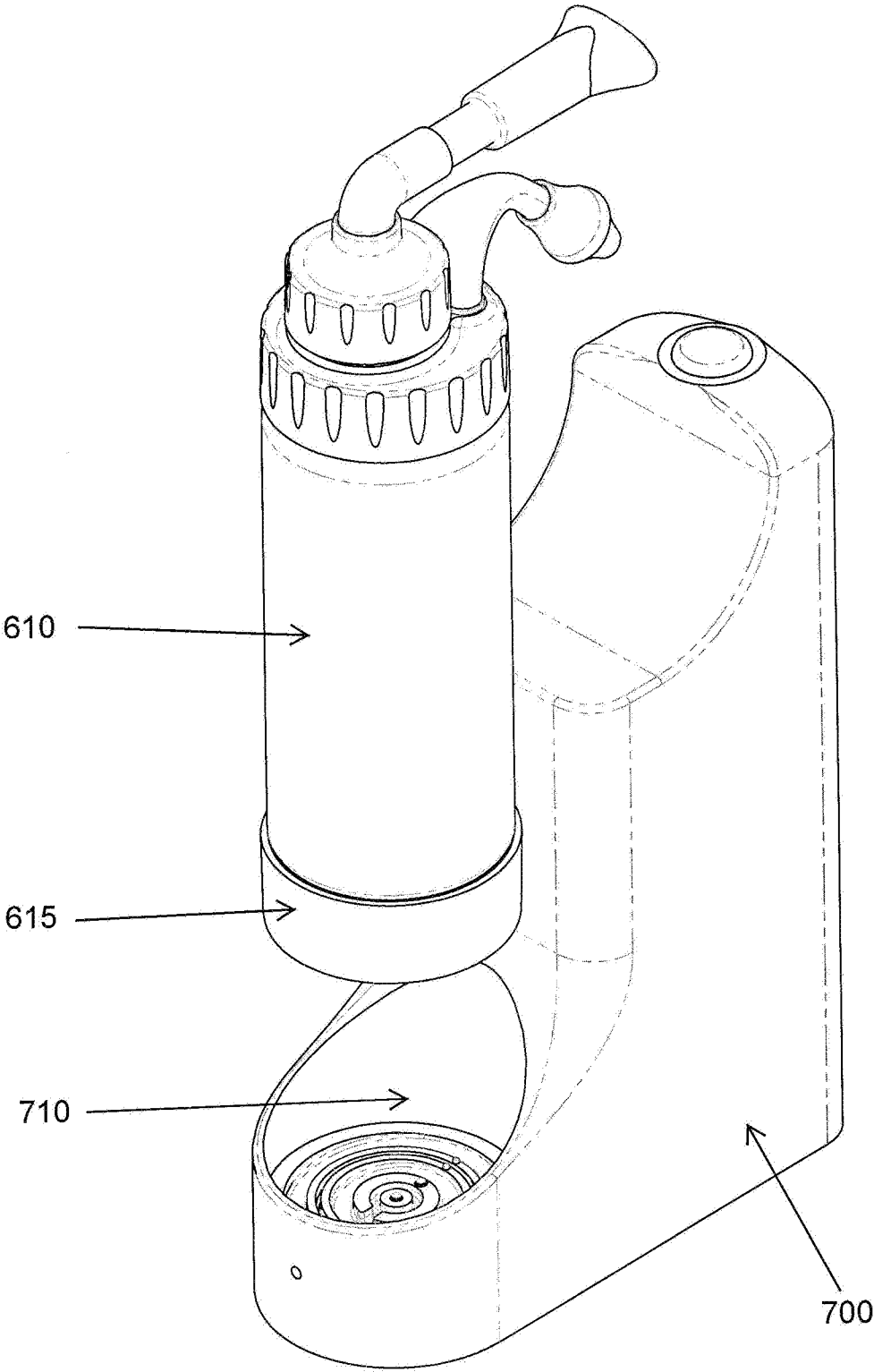


Fig. 13

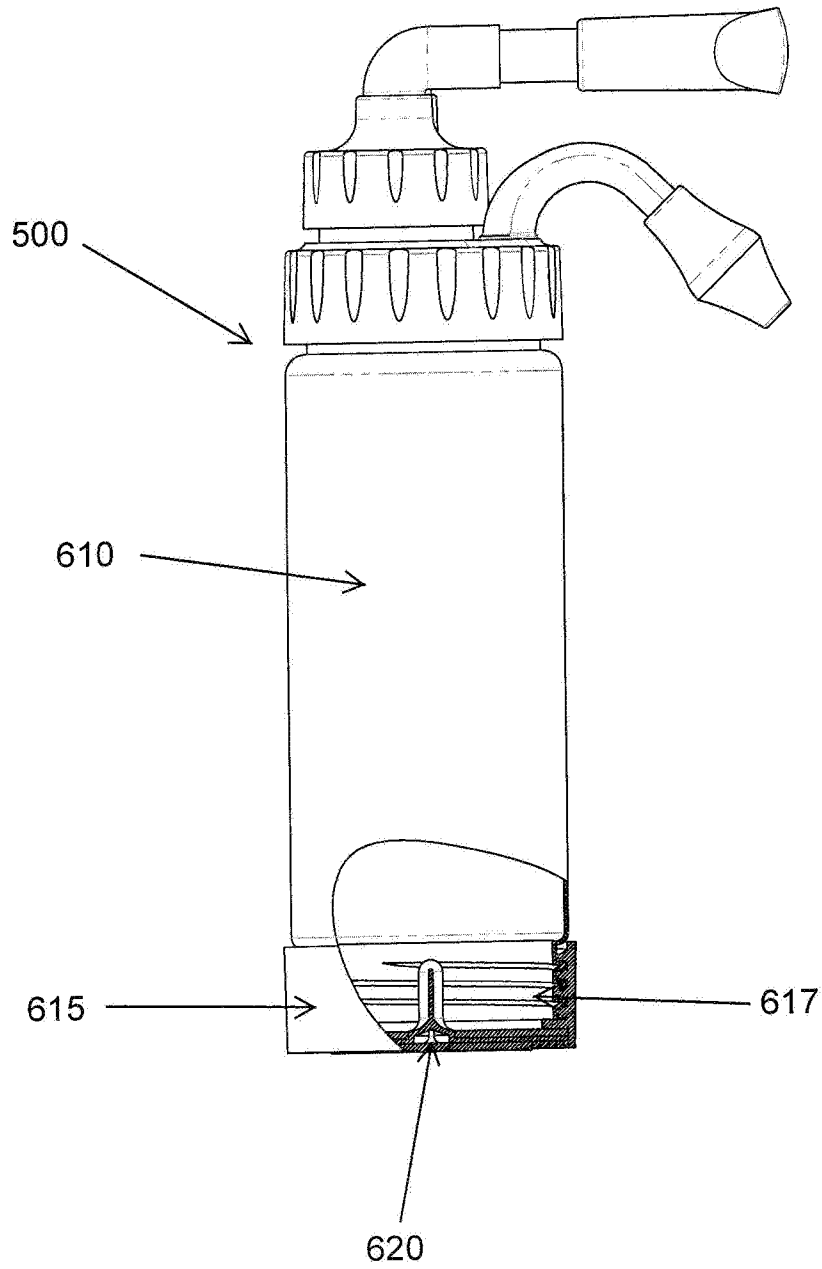
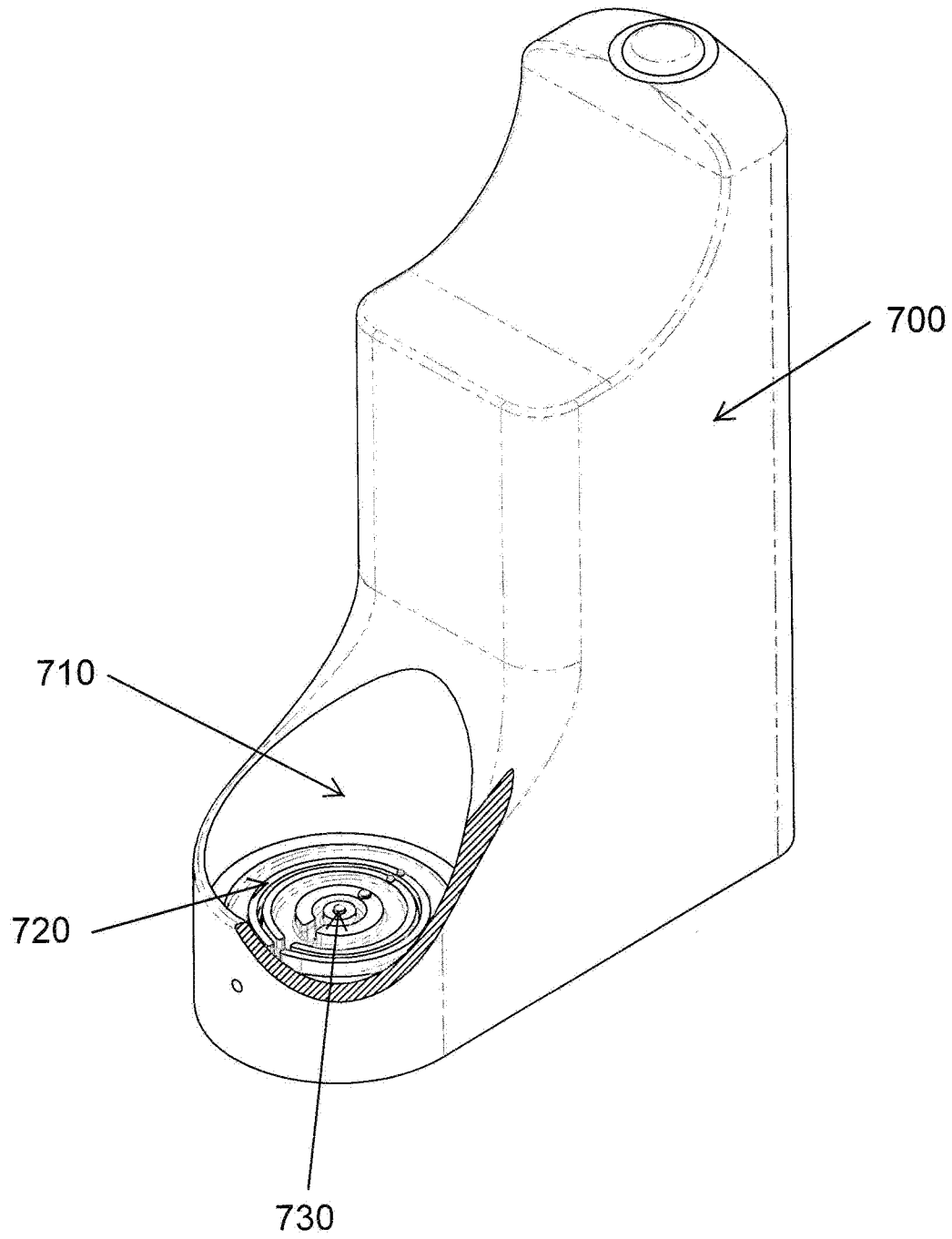


Fig. 14



INTERNATIONAL SEARCH REPORT

WO 2020/005910

International application No

PCT/UPCT/US2019/038934

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61H35/04 A61C17/02 A61M3/02 A61K9/00 A61M15/00
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61H A61C A61M A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/124491 A1 (OPTINOSE AS [NO]) 29 August 2013 (2013-08-29)	3
A	abstract; figures 1-3	1
X	----- CN 203 677 672 U (QINGDAO MUNICIPAL HOSPITAL) 2 July 2014 (2014-07-02)	1,2,4
Y	abstract; figure 1	3,6
X	----- US 5 376 072 A (KLEARMAN JEFFREY D [US] ET AL) 27 December 1994 (1994-12-27)	1
Y	claims 1-23; figures 1-8	3,6
X	----- CN 201 727 817 U (JIULONG CUI) 2 February 2011 (2011-02-02)	1
Y	claim 1; figure 1	6
Y	----- WO 2009/102976 A2 (IMMEL TIMOTHY SEAN [US]) 20 August 2009 (2009-08-20)	
	paragraphs [0095], [0111]; figure 1	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

11 September 2019

Date of mailing of the international search report

20/11/2019

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
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Authorized officer

Shmonin, Vladimir

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/038934

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

grinding means

2. claims: 7-15

removably attachable nose and mouth pieces

3. claims: 16-20

an input apparatus with a tube with a mouth piece at a first terminal end of the tube and a diaphragm at a second terminal end of the tube that connects to the input apparatus

4. claim: 21

an input apparatus with a tube having a first terminal end and a second terminal end that is connected to the input apparatus wherein a diaphragm is interposed at the second terminal end of the tube; wherein the diaphragm has a first closed position that prevents flow through the tube when pressure is asserted on the top side of the diaphragm and a second open position that permits flow through the tube when pressure is asserted on the bottom side of the diaphragm

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2019/038934

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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